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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
ALLEN, M	
ART UNIT	**PAPER NUMBER**
1812	24

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18N2/0105

DATE MAILED: 01/05/95

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☑ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☑ Claims 2-3, 11-15 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 2-3, 11-15 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

Claims 1, 4-10, and 16-21 have been canceled. Claims 2-3 and 11-15 are under consideration by the Examiner.

The information disclosure statement has not been considered because no copies of the references have been provided. It is noted that the Derynck et al. patent is already of record.

It is noted that Paper No. 23 indicates that applicant intended to submit a declaration. However, no such declaration has been received and several telephone calls by the Examiner to Mr. Kokulis and his secretary concerning submission of the declaration were not returned.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an enabling disclosure.

The specification fails to enable how to use the GDF-1 protein in the manner set forth in the specification. Claims 2-3 are drawn to DNA segments encoding mammalian GDF-1 protein. Claims 11-14 are directed to vectors and transformed host cells and claim 15 is directed to a method of producing the protein. Biological properties are alleged based upon the similarity of the GDF-1 amino acid sequence to the TGF- family. However, there is no evidence of record that this DNA sequence encodes a biologically useful protein possessing any particular properties. (See specification pages 10-11.) The similarities between GDF-1 and the TGF- family members range from 26-52% on the amino acid level and these proteins are not deemed to be predictive of the biological

properties possessed by GDF-1. The biological activities of the TGF- family are diverse and it could not be predicted which activity GDF-1 would have, if any. As such, the specification does not enable using the GDF-1 protein or DNA sequence as disclosed in the specification. For example, there is no evidence of any disease state that can be treated with this protein nor any tumors, genetic diseases, or developmental anomalies that applicant has associated with this gene or protein.

With respect to claim 15, expression of GDF-1 is described on page 6 in the description of figure 9; however, insufficient details are presented to determine what was performed. It does not appear that the protein was isolated as set forth in the claimed method. There does not appear to be a further discussion of figure 9 and the recombinant production of GDF-1 in the specification. It is deemed to be unpredictable whether the protein could be successfully produced recombinantly in the absence of a clear description of its production which the specification lacks. As such, the method of claim 15 is not sufficiently described nor enabled.

Claims 2-3 and 11-15 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 2-3 and 11-15 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly

point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 has been amended to recite "encoding a mammalian GDF-1 protein, said segment having the sequence as defined in Figure 2, 11A, or 11B." It is unclear whether only portions of the Figures encoding the amino acids of GDF-1 are being claimed or the entire DNA sequences presented in the named figures. That is, are non-coding regions intended to be encompassed by the claims and/or DNA sequences including the UOG protein?

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen, whose telephone number is (703) 308-0666. The examiner can normally be reached on Monday-Thursday from 8:00 am to 5:30 pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Garnette D. Draper, can be reached on (703) 308-4232. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Marianne P. Allen

MARIANNE P. ALLEN
PATENT EXAMINER
GROUP 1800

mpa
January 4, 1995